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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,704	05/30/2000	George Peter Lomonosoff	DOW-04647	2167
23535	7590	10/22/2003	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			SANDALS, WILLIAM O	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/580,704	LOMONOSSOFF ET AL.	
	Examiner	Art Unit	
	William Sandals	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-9 and 12-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-9 and 12-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1, 4-9 and 12-16 are pending.

The finality of the previous office action is withdrawn.

New grounds of rejection are presented below.

Applicant's request for reconsideration of the finality of the rejection of the last Office action has been considered. Applicant's request is not found persuasive. However, US Application Number 07/600,244 (Grill et al.) was abandoned before the filing date of US 5,316,931 (Donson et al.). Therefore US 5,316,931 is not a continuation in part of US Application Number 07/600,244, and the grounds of rejection in the final office action, mailed April 9, 2003 cannot be sustained, requiring withdrawal of the rejections under 35 USC 102 and 103. This fact necessitates the new grounds of rejection below.

US 5,316,931 (Donson et al.) is a continuation in part (CIP) of US Application Number 07/739,143 (Donson et al.) filed August 1, 1991. US Application Number 07/739,143 is a continuation of US Application Number 07/310,881 (Grill et al.) filed February 17, 1989. The specification of US Application Number 07/600,244 is identical to the specification of US Application Number 07/739,143 since they are both continuations of US Application Number 07/310,881. For these reasons, the fact

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pattern of the previous rejection under 35 USC 103 over US 5,316,931 (Donson et al.) in view of US Application Number 07/600,244 (Grill et al.) and US 5,437,976 (Untermohlen et al.) is valid. However, the basis of the newly made rejection below has been changed by using the teachings of the child document, US 5,316,931 (Donson et al.) which has continuity with the teachings of the CIP parent US Application Number 07/739,143.

Applicant's request for reconsideration of the finality of the rejection of the last Office action in the remarks filed August 11, 2003 at page 4, has been considered. The asserted reason for the request is that there is a "serious flaw in the examiner's analysis". It is stated that the contents of the specification of US 5,316,931 (Donson et al.) is not the same as the contents of the specification of the CIP parent, and that this difference in the contents of the disclosure between the two specifications constitutes a "hiatus of disclosure". It is stated that the "hiatus of disclosure" demonstrates a lack of continuity of disclosure between the CIP parent document and the child document, US 5,316,931 (Donson et al.). It is further stated that Examples 17 and 18 in the CIP parent document are not found in the child document US 5,316,931 (Donson et al.), that Examples 1-4 in the CIP parent document are not the same as Examples 1-4 in the child document US 5,316,931 (Donson et al.), and that the list of viruses recited in the CIP parent document has been changed in the child document US 5,316,931 (Donson et al.).

The assertion that there is a “serious flaw in the examiner’s analysis” in the remarks filed August 11, 2003 at page 4, is not found persuasive. The disclosure of the CIP parent document provides support for the disclosure in the child document US 5,316,931 (Donson et al.). The presentation of the facts in the child document US 5,316,931 (Donson et al.) have been rearranged, however, the facts relied upon in the rejection are still present in the both the CIP parent and the child document US 5,316,931 (Donson et al.). Therefore, there has been no “hiatus of disclosure”, and the argument is not found convincing.

Amendments to the claims, which are presented in the paper filed on August 11, 2003, have overcome the rejection of claims 1, 2, 7-10, 15 and 16 under 35 USC 102(e) over US 5,316,931 (Donson et al.)

The rejection of claims 1-3, 7-11 and 14-16 under 35 USC 102(e) over US Application Number 07/600,244 (Grill et al.) has been withdrawn because US Application Number 07/600,244 (Grill et al.) is not available as prior art.

Claims 9 and 12-16 stand rejected under the judicially created doctrine of double patenting as being unpatentable over claims 1-9 of US 5,874,087 and claims 22-28 of US 5,958,422. A statement in the paper filed August 11, 2003 indicates that claims 9 and 12-16 may be split out into a separate application, and then a terminal disclaimer would be filed in the separate application. No rebuttal arguments have been presented.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,874,087. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 9 and 12-16 are drawn to a genus of a method of producing a modified plant virus, while claims 1-9 of US 5,874,087 are drawn to a species of a method of producing a modified plant virus, and the species claims make the genus claims obvious.

Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 22-28 of U.S. Patent No. 5,958,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 9 and 12-16 are drawn to a genus of a method of producing a modified plant virus, while claims 22-28 of US

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5,958,422 are drawn to a species of a method of producing a modified plant virus, and the species claims make the genus claims obvious.

Response to Arguments

A statement in the paper filed August 11, 2003 at page 6, indicates that claims 9 and 12-16 may be split out into a separate application, and then a terminal disclaimer would be filed in the separate application. No rebuttal arguments have been presented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-9 and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the plant viral coat protein" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "such that there is no significant interference with the capacity of said modified plant virus to assemble". There is no definition in the claims and specification as to the metes and bounds of the term "no significant interference with the capacity of said modified plant virus to assemble". Without proper guidance, one of skill in the art would not know when the capacity of a modified virus to assemble has suffered a "significant interference". The term is not an art recognized

term, and as such the instant specification must provide the requisite guidance. In the absence of the requisite guidance, the claims are vague and indefinite.

Claim 9 recites the limitation "the viral coat protein" in line 3 of section "b)". There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the plant of claim 9" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the plant of claim 9" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the plant of claim 9" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "said modified plant virus" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "said modified plant virus" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,316,931 (Donson et al., of record) in view of US 5,437,976 (Untermohlen et al., of record).

Claims 1 and 4-8 are drawn to a plant infected with a modified plant virus. The modified plant virus comprises a nucleic acid, which encodes a foreign peptide from an animal virus inserted into a plant viral nucleic acid sequence encoding a plant viral coat protein. The foreign peptide is inserted into the coat protein such that there is no significant interference with the capacity of the modified plant virus to assemble. Claims 9 and 12-16 are drawn to a method of producing modified plant virus particles by infecting plant material with the above modified plant virus. The plant virus may be an RNA virus, or may be a comovirus. The nucleotide sequence encoding the foreign peptide may be from foot and mouth disease virus, HIV or human rhinovirus.

Donson et al. teach a plant infected with a modified plant virus (see column 6, lines 35-47). The modified plant virus comprises a nucleic acid, which encodes a foreign peptide (see column 8, lines 37-55 and column 12, lines 1-40) inserted into a plant viral nucleic acid sequence encoding a plant viral coat protein. The foreign peptide is inserted into the coat protein such that there is no significant interference with the capacity of the modified plant virus to assemble. The plant virus may be an RNA virus, or may be a comovirus (see column 2, lines 15-45 and column 9, lines 14-27). Donson et al. teach a method of producing modified plant virus particles by infecting plant material with the above modified plant virus (see column 4, lines 26-43 and

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column 6, lines 35-47). Donson et al. teach that it is desirable to use the modified plant virus to produce vaccine (column 14, lines 59-68).

NOTE:

The specification of US Application No. 07/600,244 has been provided in a previous office action. The specification of US Application No. 07/600,244 is identical to the specification of US Application No. 07/739,143 (Donson et al.). Further, the specification of US Application No. 07/310,881 is also identical to the specification of US Application No. 07/600,244, which is identical to the specification of US Application No. 07/739,143 (Donson et al.). Relevant passages in the specification of these documents are: A modified plant RNA virus (page 6, lines 7-30); A nucleic acid encoding a foreign peptide inserted into a viral nucleic acid encoding a viral coat protein (page 11, lines 27-35 and page 25, lines 13-35); A plant virus which may be a comovirus (page 12, lines 3-22); A method of producing modified plant virus particles by infecting plant material with the modified plant virus (page 32, lines 24-34 and page 37, lines 25-35).

Donson et al. do not teach that the foreign peptide is from an animal virus.

Untermohlen et al. teach the selection of nucleotide sequences, which are useful for the development of vaccines (column 4, lines 8-25). The list of obvious sources for the selection of nucleotide sequences is found at a Table 1, which includes foot and mouth disease virus, HIV virus and human rhinovirus (bottom of column 6 – top of column 7).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to combine the plant virus modified by the introduction of a

nucleotide sequence encoding a foreign peptide as taught by Donson et al. with the nucleotide sequences from animal viruses of Untermohlen et al. because Donson et al. teaches that the insertion of nucleotide sequence into the coat protein of a plant virus is useful for vaccine production and Untermohlen et al. teach the nucleotide sequences from animal viruses are useful for expression of the sequences for vaccine production. One of ordinary skill in the art would have been motivated at the time the instant invention was made to combine the modified plant virus comprising a nucleic acid encoding a foreign peptide as taught by Donson et al. with the nucleic acids useful for expressing peptides encoded by a nucleic acid from animal viruses of Untermohlen et al. for the expected benefit of the expression of a nucleotide sequence from an animal virus, which is inserted into a gene encoding a coat protein of a plant virus, where the expressed, specified protein is useful for vaccine production. Further, one of ordinary skill in the art would have had a reasonable expectation of success of expressing the foreign nucleic acid encoding a protein from an animal virus as demonstrated by Untermohlen et al. by inserting the foreign nucleic acid sequence into the nucleic acid sequence encoding the coat protein of a plant virus and expressing the protein for use in vaccine production as demonstrated by Donson et al.

Response to Arguments

Arguments presented in the paper filed August 11, 2003 at page 5 assert that the specification of 07/600,244 (which is identical to the specification of 07/739,143) does not teach the claimed embodiment wherein the foreign peptide is from an animal virus.

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This argument is not found convincing. The above rejection makes it clear that it would have been obvious to insert a nucleic acid encoding an animal virus protein of US 5,437,976 (Untermohlen et al.) into the nucleic acid encoding a coat protein in a plant virus of US 5,316,931 (Donson et al.).


Arguments regarding the lack of continuity between US 5,316,931 and US Application No. 07/739,143 have been addressed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Sandals whose telephone number is (703) 305-1982. The examiner can normally be reached on Monday through Thursday from 7:30 – 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

William Sandals


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